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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,394	05/16/2001	Naoto Miwa	SCH 1799	2377

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,394

Applicant(s)

MIWA ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12, 14-16, 18-20, 25 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) 10-12, 14-16, 18-20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. Amendment filed on April 18, 2003 has been entered. Claims 29-35 are under consideration. Claims 10-12, 14-16, 18-20, 25 stand withdrawn as they are not directed to this subgenus or the elected species of claim 17. Claims 1-28 are pending.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-32 appear to be duplicate claims as they limit the base claims in the same manner.

Similarly, claims 33-34 do not further limit their base claim 31 because they do not add an additional limiting component. The recited intended use does not elementally limit the claimed composition claims. Therefore, the claims appear to be duplicate of their base claims.

Claim 35 does not use proper Markush language. Applicant is encouraged to use proper Markush language. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. When materials recited in a claim are so related as to constitute a proper Markush

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group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper. See MPEP 2173.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 29, 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al US Patent 4,839,265.

4. Instant claims are directed to cyanine dye compounds and compositions.

Applicant is reminded that claims as drafted are not limited towards pharmaceutical or in vivo use.

Ohno disclose water-soluble cyanine dye compositions comprising all features of the generic claim 29. Specifically it contains an indole ring having a R_3 -C- R_4 functional group at corresponding positions X or Y where R_3 or R_4 are methyl groups. The corresponding L_1 - L_7 of Ohno contain substituted methyl at position L_4 . Ohno's composition further contains one or more sulfonic acid groups in the molecule corresponding the same positions as instant compounds. (col 7-8, example 13).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that example 13 of Ohno is a potassium salt not a sodium salt.

In response Examiner states that Ohno clearly discloses alkali metal salts of his compounds wherein alkali metal salts can be either Na and K (see col 3, lines 21-23). Accordingly, examples of sodium salts are explicitly disclosed. Thus, Ohno anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

5. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al US Patent 4,839,265.

Ohno teaches cyanine dyes at col 7-8, example 13. Ohno does not teach the instant alkyl chains at positions R₁₉ and R₂₀. Ohno teaches a C4 alkyl chain. The instant claim 30 is a C2 alkyl chain. Nevertheless, Ohno teaches that such alkyl chain may contain 1-5 carbons (col 3, lines 34-37).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the alkyl length of Ohno's compound from 4 to 2, because the ordinary skill in the art as taught by Ohno would have had a reasonable expectation of success in achieving the same results.

Furthermore, it has been held that homologs are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). Thus, the limitations of claim 30 are presumed *prima facie* obvious in view of Ohno's example 13.

6. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al US Patent 6,329,531 in view of Lonsky et al US Patent 6,441,191.

Turner discloses cyanine compounds encompassing the instant claims. formula V of Turner disclose such cyanine dyes wherein X and Y is $C(CH_3)_2$; R19, R20 (corresponding to instant R22, R26) are sulfate salt $-SO_3H$; R21, R22 (corresponding to instant R19, R20) are C1-C4 sulfoalkyl chain. Turner fails to teach sodium salts of his compounds.

Lonsky is merely used to show that preparing alkali metal salts of cyanine salts such as sodium salts is well practiced in the art of cyanine dyes in order to establish a suitable dye composition. (see col 2, lines 30-65; col 3, lines 54-65).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to prepare sodium salts of Turner's composition, because as taught by Lonsky, the ordinary artisan would have had a reasonable expectation of success in preparing an effective disulfonic cyanine dye derivatives.

Moreover, absence of evidence showing the contrary, where the prior art compounds were not true homologs or isomers of the claimed compound, the courts have held that the similarity between the chemical structure and properties is sufficiently close to justify a *prima facie* obviousness rejection, because one of ordinary skill in the art would have been motivated to make the claimed compounds in searching for new products. *In re Payne*, 606 F.2d. 202, 203 USPQ 245 (CCPA 1979); *In re Mayne*, 104 F.2d 1339, 41 USPQ2d 1451 (Fed. Cir. 1997).

Accordingly, modifying Turner's compounds to formulate a sodium salt thereof would have been *prima facie* obvious, because as suggested by Lonsky, and reasoned in

Mayne and Payne the ordinary artisan would have been motivated to make the claimed sodium salt formulations.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action, because the scope of the claims have been modified. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned


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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
June 21, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200